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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,865	01/18/2001	Shizuo Hattori	208753	1162

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[REDACTED] EXAMINER

LOEB, BRONWEN

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1636

DATE MAILED: 09/30/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/765,865	HATTORI ET AL.
	Examiner	Art Unit
	Bronwen M. Loeb	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 02 July 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-6 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input checked="" type="checkbox"/> Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Copy of Papers Originally Filed information.

09/765,865

The following papers have not been made part of the permanent records of the United States Patent and Trademark Office (Office) for this application (37 CFR 1.52(a)) because of damage from the United States Postal Service irradiation process:

Mailroom Stamp Date

Certificate of Mailing Date

2 July 2002

24 June 2002

Paper 11

The above-identified papers, however, were not so damaged as to preclude the USPTO from making a legible copy of such papers. Therefore, the Office has made a copy of these papers, substituted them for the originals in the file, and stamped that copy:

**COPY OF PAPERS
ORIGINALLY FILED**

If applicant wants to review the accuracy of the Office's copy of such papers, applicant may either inspect the application (37 CFR 1.14(d)) or may request a copy of the Office's records of such papers (*i.e.*, a copy of the copy made by the Office) from the Office of Public Records for the fee specified in 37 CFR 1.19(b)(4). Please do **not** call the Technology Center's Customer Service Center to inquiry about the completeness or accuracy of Office's copy of the above-identified papers, as the Technology Center's Customer Service Center will **not** be able to provide this service.

If applicant does not consider the Office's copy of such papers to be accurate, applicant must provide a copy of the above-identified papers (except for any U.S. or foreign patent documents submitted with the above-identified papers) with a statement that such copy is a complete and accurate copy of the originally submitted documents. If applicant provides such a copy of the above-identified papers and statement within **THREE MONTHS** of the mail date of this Office action, the Office will add the original mailroom date and use the copy provided by applicant as the permanent Office record of the above-identified papers in place of the copy made by the Office. Otherwise, the Office's copy will be used as the permanent Office record of the above-identified papers (*i.e.*, the Office will use the copy of the above-identified papers made by the Office for examination and all other purposes). This three-month period is not extendable.

Part of Paper No. 12

DETAILED ACTION

This action is in response to the amendment filed 2 July 2002 in which claims 1 and 4-6 were amended.

Claims 1-6 are pending.

Response to Amendment

1. The rejection of claims 1-6 under 35 USC §112, 2nd paragraph as being indefinite has been withdrawn in view of Applicant's amendment.

The rejection of claims 1-4 and 6 under 35 USC §102(e) as being anticipated by Sode has been withdrawn. See below for discussion.

The rejection of claims 1, 2, 4 and 6 under 35 USC §102(b) as being anticipated by Tamaki et al has been withdrawn. See below for discussion.

2. Claims 1-6 stand rejected under 35 USC §103(a) as being unpatentable over Takeshima et al (JP 11-243949) in view of Cameron et al (USP 5,670,343) for reasons of record and as further discussed below.

3. New grounds of rejection, necessitated by Applicant's amendment, are presented below.

Response to Arguments

4. With regard to the rejection of claims 1, 2, 4 and 6 under 35 USC §102(b) as being anticipated by Tamaki et al and the rejection of claims 1-4 and 6 under 35 USC

§102(e) as being anticipated by Sode, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that neither Tamaki et al or Sode teach that the vectors taught (pGLD3 and pTrc99A, respectively) lack the conjugative transfer function and that it must be presumed that the vectors have "the normal complement of functions". These arguments are not persuasive. Applicant does not provide any objective evidence that the plasmids lack conjugative transfer functions. Indeed, while considering this argument, the Examiner determined that neither vector possesses the mob locus. During this consideration the Examiner also determined that neither vector is a broad-host-range vector (an issue Applicant failed to address in their argument). The Examiner determined that the pGLD3 (which has pACYC177 as a parent) comprises the replicon of p15A, which is considered a narrow-range-host replicon and that the vector taught by Sode (pTrc99A) possesses the pMB1 replicon, which is a narrow-host-range replicon. The rejection based on Tamaki et al and the rejection based on Sode were therefore withdrawn in view of the determination regarding the host-range and not Applicant's argument regarding the conjugal transfer function.

5. With regard to the rejection of claims 1-6 under 35 USC §103(a) as being unpatentable over Takeshima et al in view of Cameron et al, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant mischaracterizes the Office Action with respect to the combination of the teachings on p. 5, second paragraph under "Discussion of the Rejection under 35 USC §103(a)". Specifically, Applicant states "The Office contends that it would be

obvious....to alter the plasmid...because the Cameron reference teaches the means to achieve non-mobilizable vectors by deletion of a region carrying a mob locus".

However, what was stated in the Office Action was that it would have been obvious to one of ordinary skill in the art to make pGLD3 a non-mobilizable vector by *mutating* or *deleting* the conjugative transfer function (p. 5, paragraph 10 of Office Action mailed 26 March 2002). Applicant argues that it would not have been obvious to apply the teachings of Cameron et al to the plasmid of Takashima et al because the mob gene is located close to the rep genes and that the deletion of the mob locus as taught by Cameron could result in impairment of the rep genes and thus could result in lowering the expressed activity of the enzyme.

The Cameron reference was cited to demonstrate the advantages achieved when one removes or inactivates the mob locus, including biosafety constraints and plasmid stability (col. 12, lines 48-62). Furthermore, one of ordinary skill in the art would not be dissuaded from applying the deletion approach also taught by Cameron et al as the ordinary-skilled artisan would know that the dilution series used in the deletion step (col. 10, lines 6-10) would yield a wide range of deletions (not just the 3.5 kb they selected) which permits one to screen the resulting transformants for both good replication efficiency of the plasmid as well as good expression of the encoded enzyme. Furthermore, while Cameron et al teaches in detail a method for deletion of the mob locus, one of ordinary skill in the art would be very well aware of other approaches such as mutagenesis as an alternate means to inactivate or remove the mob locus.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 1-6 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in reciting "the plasmid is expressed in bacteria of the genus *Pseudomonas*" as it is unclear if the claim is drawn to the plasmid or to a *Pseudomonas* transformant comprising and expressing the plasmid. This rejection would be overcome by amending claim 1 to recite "the plasmid is expressible in bacteria..." or "the plasmid can be expressed in bacteria....".

Conclusion

Claims 1-6 are rejected.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as

soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Tracey Johnson, Patent Analyst whose telephone number is (703) 305-2982.

Bronwen M. Loeb, Ph.D.

Patent Examiner

Art Unit 1636

September 22, 2002


REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
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